GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 812
TO BE ANSWERED ON 14TH DECEMBER, 2018

PRICING OF MEDICAL DEVICES

812. DR. PRITAM GOPINATH MUNDE:
DR. SHRIKANT EKNATH SHINDE:
SHRI ADHALRAO PATIL SHIVAJIRAO:
SHRI SHRIRANG APPA BARNE:
SHRI ANANDRAO ADSUL:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the importers' lobby is pitching for increase of 18 per cent in Maximum Retail Price (MRP) for all medical devices simultaneously making a request to the Government to rationalise the trade margins, if so, the response of the Government thereon;

(b) whether there is an urgent need for an integrated and calibrated development policy to put 'Make in India' initiative in medical devices sector in topon foreign made devices;

(c) if so, the response of the Government thereon and the steps taken in this regard;

(d) whether the Government has taken note of the reports in newspapers about unaffordable hospital bills and exorbitantly priced medical devices used in treatment which has created distrust in healthcare industry; and

(e) if so, the steps taken by the Government to address the issue?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a): The Department of Pharmaceuticals, which is mandated with the task of dealing with pricing issues of medical devices, has informed that it has not received any such representation from the industry for increase of 18 percent in medical devices.

(b) & (c): Realising the needs of medical devices sector, the Government has operationalized a sub-scheme, namely, Development of Common Facility Centre for Medical Devices (DCFC-MD). It aims to provide financial assistance to upcoming medical device parks for creation of Common Facility Centre (CFC). This move is expected to bring down the manufacturing cost of indigenous medical devices, thus making them competitive and giving a fillip to 'Make in India'. Further, Department of Pharmaceuticals has issued guidelines for implementation of Public Procurement (Preference to Make in India) Order, 2017. The Department has also clarified in the guidelines that USFDA/CE Certifications, etc. shall not be mandatory for those medical devices for which Bureau of Indian Standards (BIS) standards exist. This move is also expected to boost manufacturing of indigenous medical devices.

(d) & (e): Health is a State subject. The Government of India has, however, enacted the Clinical Establishments (Registration and Regulation) Act, 2010 for registration and regulation of the Clinical Establishments with a view to prescribe the Minimum Standards of facilities and services provided by them. Under the Clinical Establishments (Central Government) Rules, 2012 notified under this Act, the clinical establishments (in the States/Union Territories where the said Act is applicable) are inter-alia required to follow Standard Treatment Guidelines as may be issued by Central/State Governments, display their rates at a conspicuous place and charge the rates for each type of procedure and service within the range of rates determined from time to time in consultation with the State Governments. The National Council for Clinical Establishments has approved a standard list of medical procedures and a standard template for costing of medical procedures and the same has been shared with the States/UTs where the Act is applicable for appropriate action. Further action lies within the purview of the State/UT Governments as the implementation and enforcement of the said Act is within the remit of the State/UT Governments.

Currently, the Act is applicable in 11 States namely Sikkim, Mizoram, Arunachal Pradesh, Himachal Pradesh, Uttar Pradesh, Bihar, Jharkhand, Rajasthan, Uttarakhand, Assam and Haryana and all Union Territories except Delhi. Other States may adopt the Act under clause (1) of Article 252 of the Constitution.